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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Huet

For: Anti-Stick Device for Bent Injection Needle

Serial No.: 10/562,334

Filed: 5/12/2005

Examiner: Bouchelle

Group Art Unit: 3763

Attorney Docket No.: MART0890US

March 17, 2008

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This communication is responsive to the final rejection mailed November 28, 2008 in the above identified patent application.

SUMMARY OF INTERVIEW

At the outset, Applicant wishes to thank the Examiner for the courtesies extended to Applicant's attorney in an interview on March 13, 2008. Applicant discussed with the Examiner a proposed request for reconsideration of the final rejection which had informally been submitted to the Examiner on the previous day. The Examiner acknowledged that she had not considered limitations in the claims which were highlighted in the proposed request for reconsideration and that she believed that the claims were patentable over the art of record. The Examiner further indicated

that she would have to take the matter up with her supervisor before she could commit to allowing the application.

On March 17, 2008, the undersigned attorney telephoned and spoke with the Examiner who stated that she had been asked by her supervisor to conduct a further search. It was requested that a response after final rejection be submitted so that the search could be prioritized. Hence, this request is now being formally filed.

REQUEST FOR RECONSIDERATION AFTER FINAL REJECTION

Applicant respectfully requests reconsideration of the final rejection of the application. As shown below, there are several limitations in claim 1, the only independent claim in the application, which are neither found in the cited art nor mentioned in the grounds of rejection.

On June 13, 2007, a first office action on the merits was issued in which claim 1 was rejected as obvious over Knotek. It was the Examiner's contention that the only limitation of applicant's invention missing from Knotek was the requirement that the needle be bent.

On September 12, 2007, Applicant filed a response in which the claims were amended, mainly to overcome Section 112 issues. Applicant's arguments against the finding of obviousness were mainly directed to the bent needle.

On November 28, 2007, an office action was issued in which the Section 112 issues were stated to have been overcome. However,

claim 1 was finally rejected, as were all of its dependent claims, for the same reasons given in the earlier action.

The reasons given for rejection of claim 1 are as follows.

> 2. Claims 1-3,5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knotek (US 5531704). Knotek discloses a needle puncture prevention device comprising a needle 20, a protector having articulating panels 38, 40, the panels having holes 28, 64 to receive the needle, the panels forming a space sufficient to contain the distal end of the needle (see Fig. 2), two lateral lugs 60, a disk 30 of hard plastic material (col. 7, lines 9-15) that prevents slipping of the needle. The device comprises a cap 66 for covering the needle.
>
> 3. Claim 1 differs from Knotek in calling for the needle to be bent. At the time of invention it would have been an obvious matter of design choice to include a bent needle. The device on Knotek is capable of protecting a bent needle as well as a straight needle as disclosed by applicant.

The patentably distinguishing limitations of claim 1, which are absent from the prior art and which were not mentioned in the rejections are discussed below.

Applicant's device is designed to enable a bent needle to be pulled from the skin without upsetting an injected chamber implanted under the skin. Knotek does not mention a bent needle or a subcutaneous chamber. Even if it may be obvious to substitute a bent needle for a straight one, the construction of a device for safely inserting and removing a bent needle is different and not obvious.

Applicant's device has lateral lugs which can be lifted and pulled upwardly while pressure is exerted on two other lugs to

stabilize the chamber as the needle is pulled from it (See Figs. 10 and 11).

Claim 1 recites

> said needle-holding panel comprising two lateral lugs which can be lifted to permit manual gripping of said device at the time of puncture and at the time of withdrawal of said needle,
>
> said base panel comprising a first pair of opposite lateral branches having a curvature for facilitating application of said first pair of branches on the skin in line with said implanted chamber.
>
> a second pair of opposite lateral branches of said base panel capable of being bent by two fingers of one hand in order to press said second pair of branches onto the skin and said chamber for holding said chamber in place when the operator withdraws said needle. . .

Knotek discloses no similar structure. Moreover, the elements 60 of Knotek which the Examiner refers to as "lateral lugs" are actually finger tabs used for expanding the parallelogram construction of Knotek. As stated at column 5, line 4 of Knotek

> To enclose the needle (20) and needle tip (46) in the sleeve (10), the user manually squeezes the outwardly extending finger tabs (60) toward each other and thereby biases the sidewall living hinges into a closed position. The needle tip (46) is engaged by the ribs (30) and (32) and the finger tabs (60) now extend inwardly to the sleeve.

Knotek is not concerned with the withdrawal of a bent needle or the presence of a subcutaneous chamber. With Knotek's device, a needle mounted on a needle hub is inserted through the skin. The needle is simply withdrawn by grasping the needle hub or syringe to which the hub is attached and pulling it. Thereafter, "the user

manually squeezes the outwardly extending finger tabs (60) toward each other and thereby biases the sidewall living hinges into a closed position." Thus the tabs 60 are used to open the parallelogram of Knotek's device to cover the tip of the needle.

Knotek's tabs 60 cannot be used to pull the needle from the skin. If they could be pulled to remove the needle from the skin, the dangerous tip of the needle would be exposed. That is, the parallelogram of Knotek's device would not open into a rectangle as shown in Fig. 7B of Knotek to protect the needle tip.

Knotek's tabs 60 cannot "be lifted to permit manual gripping of said device at the time of puncture and at the time of withdrawal of said needle". The tabs 60 are diagonally spaced and face in opposite directions. It would take two hands to grip the tabs leaving no free hand to grasp the needle hub or syringe. Moreover, once Knotek's parallelogram is expanded the tabs 60 face inwardly toward the needle, making them inaccessible for gripping to remove the needle.

Also, unlike Knotek's device, applicant's device assumes a very low profile conforming to the shape of the site at which it is applied. It has no significantly vertical components, such as Knotek's hub housing 24. Accordingly, in applicant's device a curvature is imparted to the overlying panels so that when one is bent onto the other they conform to and closely hug the skin. Claim 1 further recites,

> said needle-holding panel and said covering panel being contiguous, respectively, with

said first pair of branches of said base panel and

having a curvature which is the opposite of the curvature of said first pair of branches so as to match the curvature of said first pair of branches when they are folded down onto said base panel.

There is no disclosure or hint of the aforementioned limitations of claim 1 in the art cited against claim 1. For the foregoing reasons, it is respectfully submitted that claim 1 is patentable over the art of record, as are claims 2-8 which depend from claim 1. Reconsideration of the final rejection, and allowance of the application are, therefore, respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance. Early and favorable action is earnestly solicited.

An unpaid fee required to keep this case alive may be charged to deposit account 06-0735.

Respectfully Submitted,

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